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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DISCUS DENTAL, LLC
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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

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01/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/039,935	Applicant(s) MONTGOMERY, ROBERT ERIC	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-58, 61-65, 67-76 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-58, 61-65, 67-76 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed October 22, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The instant claims have a priority date of September 25, 1996. The provisional application filed September 25, 1995 does not support all the limitations of the instant claims. This action is made NON-FINAL.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 56-58, 61, 63, 64, 67-73, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,650).

Williams et al. disclose two part oral compositions wherein one part comprises peroxide or a peroxide releasing component and the second part comprises bicarbonate. The compositions are formulated into gels and pastes and may be kept isolated in a separate compartment of a dispenser such as those disclosed by Schaeffer (US 4,849,213), which shows a dispenser comprising a compartment where the two components mix before being dispensed from the dispenser (Fig. 1 of Schaeffer). The mixture of the two components will provide a composition with a pH ranging from 7.0 to 9.5 (col. 4, lines 3-9). The peroxide releasing component includes an alkali metal

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percarbonate. The compositions may also comprise tartar control agents such as disodium pyrophosphate (col. 4, lines 47-58). Humectants include polyethylene glycol and may comprise 25 to 90% by weight and water may comprise 3 to 30% by weight. The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer.

Collin et al disclose a multiple barrel dispensing device for intermixing at least two viscous materials and for dispensing the mixed product in a preferred volumetric ratio. The device comprises a syringe having a plurality of elongated storage compartments for independently storing the material to be intermixed and a common head having a separate channel extending from each compartment for discharging stored materials from a common discharge end of said head (col. 2, lines 8-10). It further comprises a nozzle having a common static mixing element. The reference differs from the instant claims insofar as it does not disclose the compositions recited in the instant claims.

It would have been obvious to one of ordinary skill in the art to have used the dispenser comprising the static mixer to dispense the compositions of the primary reference motivated by the desire to use a dispenser that intermixes at least two viscous materials and that dispenses the mixed product in a preferred volumetric ratio, as disclosed by the secondary reference.

In regards to the amount of water in the compositions in claim 61, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally

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involves the application of no more than routine skill in the art. See MPEP 2144.05, II. It would be obvious to one of ordinary skill in the art to have adjusted the amount of water to at least 70% water by weight motivated by the desire obtain a compositions with optimal efficacy.

In regards to the peroxide component being anhydrous in claims 71-76, percarbonates react with water to form hydrogen peroxide¹. Omission of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04, II. It would have been obvious to one of ordinary skill in the art to have removed water from the compositions when using percarbonates or made anhydrous compositions when using percarbonate motivated by the desire to inhibit the formation of hydrogen peroxide prematurely and ensuring a stabilized composition.

2) Claims 62, 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,650) as applied to claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 in further view of Burke et al. (US 5,292,502).

The primary and secondary references, Williams et al. and Collin et al. are discussed above. Williams et al. disclose sodium bicarbonate should be incorporated into the compositions in order to bring the pH of the combined compositions from about 7.0 to about 9.5 (col. 4, lines 3-10). The references differ from the instant claims insofar

¹ Winston et al. US 4,812,308 disclose when water is introduced to sodium percarbonate is contacted with water, it rapidly releases hydrogen peroxide (col. 2, lines 48-55).

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as they do not disclose the pH adjusting agents are alkali metal carbonates and hydroxides.

Burke et al. discloses non-irritating dentifrices and is used as a general teaching to disclose agents used to adjust pH to 4.5 to 9. These include sodium hydroxide, sodium citrate, benzoate, carbonate or bicarbonate. The reference differs from the instant claims insofar as it does not disclose a two part composition wherein one part comprises a hydrogen peroxide containing compound.

It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. See MPEP 2144.06 II. It is also prima facie obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used sodium hydroxide or sodium carbonate in place of or in combination with sodium bicarbonate in the compositions of the primary reference based on the prior art's recognition that such species are equivalent in function, as supported by cited precedent.

3) Claims 56-57, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viscio (US 5,302,375) in view of Collin et al. (US 5,033,650).

Viscio discloses compositions comprising sodium percarbonate in a non-aqueous carrier. The composition may be formulated into two parts wherein the first part is a non-aqueous composition comprising a percarbonate and the second part is an aqueous composition comprising acetylsalicylic acid. The compositions comprise 40 to 70% water (col. 4, lines 60-63). The mixing of the two components will result in a mixture having a pH of less than 10 and generally in the range of from about 8.0 to about 9.0 (col. 3, lines 60-65). The pH of the acid comprising component may be adjusted to 5.0 to about 6.5 with components such as citric acid (col. 4, lines 1-6). The reference also discloses using sodium hydroxide to adjust comparative compositions comprising acid to increase the pH. Gelling agents such as Carbopol 941 (Example 5) are also used in the formulations and polyethylene glycol is included as a humectant. Other components include anti-tartar agents such as tetra sodium pyrophosphate (which is also a base²) and dialkali metal pyrophosphates, and peroxide stabilizers such as ethylenediaminetetraacetic acid, diethylene triaminepentaacetic acid, phosphonates such as DEQUEST (col. 6, lines 9-30).

The reference differs from the instant claims insofar as it does not disclose a dispenser comprising a static mixer.

Collin et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the types of toothpaste or its components that may be dispensed from the dispensers.

² Drucker, US 4,895,721 discloses tetra sodium pyrophosphate is a base that may be used to adjust pH (col. 3, lines 9-14).

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It would have been obvious to one of ordinary skill in the art to have used the dispenser comprising the static mixer to dispense the compositions of the primary reference motivated by the desire to use a dispenser that intermixes at least two viscous materials and that dispenses the mixed product in a preferred volumetric ratio, as disclosed by the secondary reference.

In regards to claims 62, 75 and 79, it would have been obvious to use sodium hydroxide in the acid component of the compositions to ensure the compositions were at the desired pH as supported by MPEP 2144.07 (see above).

Obvious Type Double Patenting (New Rejection)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56-58, 61-65, 67-76 and 78-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 and 18-21 of copending Application No. 11/256654 in view of Collin et al. (US 5,033,650). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims comprise two part compositions wherein the first formulation comprises a hydrogen peroxide containing component and the second formulation comprises a pH adjusting agent. The copending claims recite the two formulations are mixed together prior to use. The claims differ from one another insofar as the copending claims recite a chelating agent in the independent claim and do not recite a static mixer.

Collins et al. is discussed above and differs from the instant claims insofar as it does not disclose the compositions recited in the claims.

It would have been obvious to one of ordinary skill in the art to have used a multi-chambered vessel to deliver the compositions of the copending claims motivated by the desire to use a vessel that could mix the formulations together prior to use and that dispenses the mixed product in a preferred volumetric ratio, as disclosed by the Collins et al.

This is a provisional obviousness-type double patenting rejection.

Claims 56-58, 61-65, 67-76 and 78-81 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/

Examiner, Art Unit 1612

/Frederick Krass/

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